# In the United States Court of Federal Claims Office of special masters No. 21-630V

CARMEN KIENOW,

Chief Special Master Corcoran

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: May 1, 2024

Anne Carrion Toale, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for Respondent.

## FACT RULING ON ONSET AND SITUS<sup>1</sup>

On January 12, 2021, Carmen Kienow filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"), alleging that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on September 26, 2019. Pet. at 1, ECF No. 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

<sup>&</sup>lt;sup>1</sup> Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find it more likely than not that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination, and that the subject vaccination was administered in Petitioner's right deltoid, as alleged.

## I. Relevant Procedural History

After initiating her claim, Petitioner filed an amended petition acknowledging that her vaccination record reflects the subject vaccine was administered in the left deltoid, rather than the right shoulder, as alleged. ECF No. 5. She also filed her vaccination and medical records, a witness declaration, and a statement of completion. ECF Nos. 7-8, 12, 15-17. Petitioner subsequently filed additional records, including those received in response to a subpoena served upon CVS pharmacy for Petitioner's vaccination record. ECF Nos. 18, 20, 23. Petitioner thereafter submitted a declaration addressing the onset of her injury, a Vaccine Adverse Events Reporting System ("VAERS") report, and additional medical records. ECF Nos. 27-28, 30-31, 35-36.

In December 2022 (over one year after this case's activation and assignment to SPU), while this case awaited Respondent's medical review, Petitioner filed a motion for a fact hearing regarding the situs of her vaccination and the onset of her injury. ECF No. 40. Along with the motion, Petitioner submitted a supplemental declaration and physical therapy ("PT") records. ECF No. 41. In March 2023, Respondent filed a status report stating this case was not appropriate for compensation and requesting to file a Rule 4(c) Report. ECF No. 42.

Respondent filed his Rule 4(c) Report on May 9, 2023, arguing that Petitioner had failed to show a Table injury because her medical records did not support the conclusion that the onset of her pain occurred within 48 hours of vaccination. Respondent's Report at 12, ECF No. 43. Respondent further argued that Petitioner's medical records reflect that when she did report shoulder pain, she noted the date of onset as "about a week" or "a few days" post vaccination. *Id.* at 13 (citing Ex. 4 at 7; Ex. 7 at 3). More so, Petitioner reported her pain beginning in October 2019 – or five days post vaccination at the earliest. *Id.* (citing Ex. 19 at 3). Additionally, Respondent disputed that Petitioner's pain and reduced range of motion ("ROM") were limited to the shoulder in which the vaccination was administered, as her vaccination record from CVS pharmacy states that the vaccine was administered into her left arm. *Id.* at 14 (citing Ex. 1 at 3). Despite these arguments, Respondent acknowledged that Petitioner's November 7, 2019 complaint of shoulder pain to the vaccine administrator (resulting in the creation of a VAERS report), documented the onset of pain occurring the same day as her receipt of a flu vaccination in the right arm. *Id.* at 13-14 (citing Ex. 33 at 4-5).

Petitioner was subsequently ordered to file any outstanding evidence and a brief on onset and situs. Sched. Order, docketed May 9, 2023. On July 10, 2023, Petitioner filed a second amended petition, a supplemental vaccination record, and a motion for findings of fact regarding time of onset and site of vaccination (with a supporting memorandum). ECF Nos. 46-49. Respondent filed his responsive brief on September 11, 2023, and Petitioner subsequently filed her reply one week later, on September 18, 2023. ECF Nos. 50-51. Petitioner submitted updated medical records in April 2024. ECF No. 52. This matter is now ripe for consideration.

# II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at \*19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014). The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

## III. Relevant Factual Evidence<sup>3</sup>

On September 26, 2019, Petitioner (then 56 years old) received a flu vaccine in her "left deltoid." Ex. 1 at 3. Indeed, Petitioner's vaccination record contains a computerized entry for the site of vaccine administration. See id.; see also Ex. 43 at 2. Despite this entry, Petitioner contends that she received the subject vaccination in her right deltoid "because she is left-handed." See, e.g., Pet. ¶ 1; Am. Pet. ¶ 1.

Petitioner attests that she received the subject vaccination on September 26, 2019, and that she "usually ha[d] some pain after a flu shot, but this pain persisted and kept getting worse, and worse." Ex. 32 ¶¶ 1-2. She describes symptoms including "a deep ache in [her] deltoid, the back of [her] shoulder, and a dull ache down [her] arm." *Id.* ¶ 2.

Six weeks post vaccination, on November 7, 2019, Petitioner contacted CVS pharmacy reporting right shoulder pain beginning the night of the subject vaccination. Ex. 34. Based on this complaint, the pharmacy filed a VAERS report. See id.; see also Ex. 32 ¶ 2. The VAERS report was submitted by the vaccine administrator at CVS pharmacy, based on information provided by Petitioner. See generally, Ex. 33. The VAERS report lists the date of onset as "2019-09-26" with the "days to onset" as "0." Ex. 34 at 1. The report further explains that Petitioner "received [the] flu shot in [her] right deltoid" and her "muscle soreness and pain became obvious the same night of administration (9/26/19)." Id. More so, Petitioner's "pain has no [sic] gone away or felt better, 6 weeks post-

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<sup>&</sup>lt;sup>3</sup> Only those facts relevant to site of vaccination and onset will be discussed herein.

vaccination." *Id.* The report advises Petitioner to "follow up with her primary doctor if pain persists." *Id.* 

On November 8, 2019, Petitioner had a telemedicine follow-up with her neurologist for pre-existing focal epilepsy and migraines. Ex. 27 at 213. She did not complain of shoulder symptoms during this visit. See *id*. Likewise, on December 27, 2019, Petitioner was treated for sinusitis via a virtual urgent care visit; she did not mention complaints related to either shoulder during this visit. Ex. 23 at 8-9.

In her declaration, Petitioner addresses "why it took a while for [her] to visit the doctor after the initial shot." Ex. 32 ¶ 3. Petitioner describes her job responsibilities, requiring frequent travel without reprieve until "the holidays." *Id.* ¶¶ 3-4. According to Petitioner, this left her "with little to no time for self-care[.]" *Id.* ¶ 3. As support, Petitioner includes her travel itinerary between October 11, 2019, and December 25, 2019. *See id.* ¶ 4. Petitioner attests that when her doctor's office re-opened after the holidays, she was able to "tend to . . . the awful pain in [her] right arm" on January 3, 2020. *Id.* ¶ 3.

Over three months post vaccination, on January 3, 2020, Petitioner presented to her primary care provider ("PCP") stating she "received her flu shot in September of last year and then *about a week later* she started [having] this slight swelling and pain in the injection site." Ex. 4 at 7 (emphasis added). The note does not specify which arm was symptomatic. See *id.* An examination revealed swelling and discoloration indicating a possible infection and Petitioner was prescribed antibiotics. *Id.* 

On January 17, 2020, Petitioner followed up with her PCP because she "continue[d] to have the problem with her right shoulder." Ex. 4 at 9. Petitioner's PCP did not "think that [Petitioner's] shot and [sic] anything to do with her right shoulder problem." *Id.* Rather, the PCP opined that Petitioner "developed acute tendinitis of her right shoulder which is coincidental with her getting the flu shot." *Id.* Petitioner received a steroid shot in her right shoulder. *Id.* 

Petitioner presented to an orthopedist on February 7, 2020, complaining of "right shoulder pain, with onset of *a few days* after her flu shot." Ex. 7 at 3 (emphasis added). Petitioner also "state[d] her flu shot was mid-September 2019." *Id.* Petitioner described relief from her steroid injection but an examination revealed tenderness to palpation and positive impingement signs. *Id.* at 3-4. Following an x-ray showing type II acromion, Petitioner was diagnosed with right shoulder subacromial impingement. *Id.* at 4. PT and over-the-counter remedies were recommended. *Id.* 

On February 20, 2020, Petitioner presented for an initial PT evaluation of her right shoulder pain. Ex. 19 at 3. Petitioner reported that her "[right] shoulder pain [] began around October 2019 following a flu shot." *Id.* Further treatment with PT was recommended and Petitioner attended four additional sessions through March 12, 2020. *Id.* at 3-11. Petitioner subsequently moved after being laid off by her employer. Ex. 2 at 184; Ex. 19 at 23.

On June 8, 2020, approximately eight months post vaccination, Petitioner presented to a new PCP (via telemedicine appointment) to establish care and "for ongoing shoulder pain." Ex. 2 at 184. The physician noted the "pain is present in the right shoulder" and that "[t]he current episode started more than 1 month ago (last September)." *Id.* Petitioner told her PCP that she had started PT but "[d]id not finish [] due to covid [sic] precaution." *Id.* at 187. Petitioner's shoulder pain was assessed as SIRVA and the physician noted that the "[v]accine was in September 2019." *Id.* at 185-87. The physician further noted that Petitioner had "a lawyer working on her case." *Id.* at 187.

Petitioner presented to a new orthopedist on June 10, 2020, to address her right shoulder pain. Ex. 8 at 24. Petitioner reported that "she had an adverse reaction from a vaccine injection in her shoulder." *Id.* She further reported that she had a cortisone injection "which was given incorrectly by her PCP[.]" *Id.* As a result of "the damage" caused by this improper injection, Petitioner stated that she had to stop attending PT. *Id.* Petitioner underwent an examination and x-ray of her right shoulder; she was subsequently diagnosed with right shoulder pain. *Id.* at 25-26. The physician administered a steroid shot to Petitioner's right shoulder and referred her to PT. *Id.* at 26-27.

During Petitioner's initial PT evaluation with a new physical therapist on June 24, 2020, Petitioner reported "right shoulder pain after a vaccine injection was placed in her shoulder bursa causing pain, swelling, and shoulder dysfunction for months." Ex. 18 at 49. The onset date was listed as "09-01-19." *Id.* Petitioner attended nineteen additional PT sessions for her right shoulder from June 24, 2020, through January 21, 2021. *Id.* at 1-52.

Beginning on July 21, 2020, Petitioner began complaining of left arm and elbow pain, in addition to improving right shoulder symptoms. See, e.g., Ex. 27 at 120-21, 138-44; Ex. 8 at 10-13, 20-23; Ex. 18 at 1, 9-12, 19. There was some dispute regarding Petitioner's left elbow diagnosis; however, thrombophlebitis and self-resolving vulvitis were ultimately suggested as potential diagnoses. See Ex. 8 at 8, 12, 19. Petitioner received care for her left arm and elbow symptoms throughout 2020 and into 2021. See, e.g., Ex. 27 at 18, 30-33, 120-21; Ex. 8 at 16; Ex. 18 at 9-12.

On July 12, 2022, Petitioner returned to PT complaining of right shoulder pain. Ex. 40 at 4. Petitioner reported that she "received a vaccine in September of 2019 that was administered incorrectly and eventually caused bursitis. Since then[,] she has had PT for both the left and right shoulder." *Id.* The physician noted that Petitioner "most recently had a flare up of the [right] shoulder after she was gardening in April[,]" and it had been painful since then. *Id.* Petitioner attended additional PT for her right shoulder through September 28, 2022. *Id.* at 11-51.

On October 7, 2022, Petitioner returned to her orthopedist for evaluation of ongoing right shoulder pain. Ex. 38 at 7. The physician noted that Petitioner's pain "ha[d] been present since 2019. This began with a specific trauma or inciting event – she reports a SERVA [sic] injury." *Id.* Following an examination and x-ray of the right shoulder, the orthopedist opined that Petitioner was "suffering from right shoulder pain due to adhesive capsulitis" and a possible rotator cuff tear. *Id.* at 8-11.

Petitioner's medical records show a return to PT on January 31, 2024. Ex. 45 at 2. She reported "[right] shoulder pain as a result of SIRVA from an injection placed incorrectly within shoulder joint in 2019." *Id.* Further PT was recommended, and Petitioner completed 13 additional sessions through March 19, 2024. *Id.* at 3-59. No additional medical records have been filed.

In addition to her own declarations, Petitioner has submitted a witness declaration from Jill Kienow.<sup>4</sup> Ex. 24. The witness declaration does not address onset but notes that "[a]round Christmastime 2019," Petitioner was "having a hard time . . . putting her seatbelt on or reaching for the car door handle with her right arm." *Id.* ¶¶ 1-2.

## IV. Findings of Fact

I am resolving the fact disputes in question on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide many matters on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the issue. See 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). Indeed, the decision to rule on the record in lieu of a hearing has been affirmed on appeal. Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2020); Hooker v. Sec'y of Health & Hum. Servs., No. 02-472V, 2016 WL 3456435, at \*21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld).

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<sup>&</sup>lt;sup>4</sup> The witness declaration does not state Jill Kienow's relationship to Petitioner.

Here, I am able to decide the two disputed fact issues without holding a live hearing featuring witness testimony. Accordingly, Petitioner's motion for fact hearing is **DENIED**.

## A. Onset

A petitioner alleging a SIRVA claim must show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)), and that her pain began within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)). Respondent argued that "in addition to the significant length of time between [P]etitioner's receipt of the flu vaccination and her first report of right shoulder pain, there are inconsistencies in [her] reports of her onset date that impact the credibility of her reports." Respondent's Response at 13. Respondent characterizes Petitioner's VAERS report as an "ex post facto statement made to a non-treater[,]" and thus should not be considered probative evidence of her injury beginning within 48 hours of the subject vaccination. *Id.* at 14.

Respondent's arguments regarding the proper evidentiary weight to give the VAERS report are not persuasive. Indeed, the VAERS report (noting onset of pain the same night of the subject vaccination on "9/26/19," and continuing for six weeks) was authored six weeks post vaccination – on November 7, 2019 – and is the earliest contemporaneous record of shoulder pain in this case, and yet it supports 48-hour onset. While applicable Program case law has repeatedly emphasized that VAERS reports are not particularly reliable evidence of *causation*, 5 the same is not true when they are offered to resolve a question of *fact*. Here, this reporting provides support for a close-in-time onset, consistent with the Table timeframe.

I also reject Respondent's contention that because Petitioner did not seek treatment for over three months post vaccination (on January 3, 2020), she cannot establish Table onset. This in and of itself is not dispositive, since I have found in other cases that even *greater* delays did not undermine an otherwise-preponderantly-established onset showing consistent with the Table. See, e.g., Tenneson v. Sec'y of Health & Hum. Servs., No. 16-1664V, 2018 WL 3083140, at \*5 (Fed. Cl. Spec. Mstr. Mar.

<sup>&</sup>lt;sup>5</sup> See, e.g., Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 559 (2006) (stating that the Court has "uniformly upheld the Chief Special Master's concerns about the reliability of VAERS data"); Ryman v. Sec'y of Health & Hum. Servs., 65 Fed. Cl. 35, 39-43 (2005) (affirming the special master's finding that a VAERS report may be biased toward pre-existing notions of adverse events); Capizzano v. Sec'y of Health & Hum. Servs., 63 Fed. Cl. 227, 231 (2004) (affirming that VAERS data has "extremely limited value to prove causation due to the manner in which it is collected, the lack of confirmation of the reported information[,] and lack of any systemic analysis."), rev'd on other grounds, 440 F.3d 1317 (Fed. Cir. 2006); Bender v. Sec'y of Health & Hum. Servs., No. 11-693V, 2018 WL 3679637, at \*31 (Fed. Cl. Spec. Mstr. July 2, 2018) (noting that "[b]ecause it is a passive reporting system . . . special masters do not typically afford great weight to VAERS data in determining causation" and that special masters' evaluations of the deficiencies of such evidence have been affirmed).

30, 2018), *mot. for rev. denied*, 142 Fed. Cl. 329 (2019) (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); *Williams v. Sec'y of Health & Hum. Servs.*, No. 17-830V, 2019 WL 1040410, at \*9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because a petitioner underestimated the severity of her shoulder injury). Delay in seeking treatment does bear on the overall severity of the injury, but is not per se evidence of a non-conforming onset.

Likewise, the fact that Petitioner sought care with two treaters between the date of her vaccination and the January 3, 2020 visit does not detract from her arguments on onset. Notably, one such visit occurred the day after Petitioner submitted her VAERS report (on November 8, 2019), but the record notes do not contain complaints of shoulder pain. See Ex. 27 at 213. However, as Petitioner notes, this visit was with a neurologist for chronic issues, and was thus not an occasion to complain of other health issues. The same is true of Petitioner's December 2019 urgent care visit for sinusitis. See Ex. 23 at 8-9. (I will note, however, Petitioner's ability to seek care for non-shoulder related issues during this time is somewhat inconsistent with her affidavit, wherein she describes shoulder pain but a schedule too engrossing for "self-care." Ex. 32 ¶¶ 3-4. This evidence is thus further supportive of the conclusion that Petitioner's SIRVA was mild).

Some of Petitioner's records do suggest an onset occurring outside of the 48-hour period. But the totality of the evidence still preponderates in Petitioner's favor. In fact, Petitioner's reports of pain beginning "about a week" or "a few days" post vaccination are not wholly inconsistent with Petitioner's earliest-in-time report of onset beginning the same night as the subject vaccination, and persisting until her November 7, 2019 report. See Ex. 34; Ex. 4 at 7; Ex. 7 at 3.

The record also establishes that Petitioner consistently and affirmatively associated her right shoulder pain to the September 2019 vaccination – first in the VAERS report, and then at her first post-vaccination visit for shoulder complaints on January 3, 2020, and thereafter as well. See, e.g., Ex. 4 at 7 (a January 3, 2020 note stating that Petitioner "received her flu shot in September of last year and then about a week later" experienced pain); Ex. 7 at 3 (a February 7, 2020 note reporting right shoulder pain "with onset of a few days after her flu shot"); Ex. 2 at 184 (a June 8, 2020 PCP note complaining of shoulder pain and noting the "[v]accine was in September 2019"); Ex. 40 at 4 (a July 12, 2022 PT note stating onset was after receiving "a vaccine in September of 2019"); Ex.

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<sup>&</sup>lt;sup>6</sup> See, e.g., Ex. 4 at 7 (a January 3, 2020 PCP note stating pain and swelling "about a week" after her vaccination); Ex. 7 at 3 (a February 7, 2020 orthopedic note stating her shoulder symptoms began "a few days" post vaccination); Ex. 19 at 3 (a February 20, 2020 PT note reflecting pain beginning "around October 2019" or approximately five days post vaccination, at the earliest).

38 at 7 (an October 7, 2022 orthopedic note describing pain "present since 2019[,]" which was "a SERVA [sic] injury"); Ex. 45 at 2 (a January 31, 2024 PT note of pain "as a result of SIRVA from an injection placed incorrectly within shoulder joint in 2019"). Petitioner's medical records thus provide preponderant support for a close-in-time onset.

#### B. Site

Based on the above evidence, it appears more likely than not that Petitioner's September 26, 2019 flu vaccine was administered in her right shoulder, as alleged. As the above-referenced medical entries establish, when seeking medical treatment on every post-vaccination occasion, Petitioner consistently reported right shoulder pain (which she also attributed to her September 2019 vaccination), and she underwent diagnostic procedures, physical therapy exercises, and treatment of the right shoulder. See, e.g., Ex. 2 at 184-88; Ex. 4 at 7-9; Ex. 7 at 3-4; Ex. 19 at 3-23.

I acknowledge that the vaccine administration record *itself* memorializes a different site of the administration of Petitioner's flu vaccine. Ex. 1 at 3. But the record is an automated, computer-generated, electronic entry. *See id.* It is not unusual for the information regarding situs of vaccination set forth in this kind of document to be incorrect.<sup>8</sup> In many instances, the information regarding situs is recorded prior to vaccination and is not subsequently corrected, even if the vaccine is then administered in the opposing arm.<sup>9</sup> Thus, although such records are unquestionably the first-generated documents bearing on the issue of site, they are not *per se* reliable simply because they come first. In fact, I have previously determined that the very nature of vaccination record creation provides some basis for not accepting them at face value. *See*, e.g., *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-881V, 2022 WL 2284311, at \*4 (Fed. Cl. Spec. Mstr. May 13, 2022). More so, I routinely give greater weight to vaccination records that

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<sup>&</sup>lt;sup>7</sup> This Ruling does not address Petitioner's left arm and/or elbow complaints and whether such symptoms are related seguela of Petitioner's post-vaccination right shoulder condition.

<sup>&</sup>lt;sup>8</sup> See, e.g., Arnold v. Sec'y of Health & Hum. Servs., No. 20-1038V 2021 WL 2908519, at \*4 (Fed. CL. Spec. Mstr. June 9, 2021); Syed v. Sec'y of Health & Hum. Servs., No. 19-1364V, 2021 WL 2229829, at \*4-5 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); Ruddy v. Sec'y of Health & Hum. Servs., No 19-1998V, 2021 WL 1291777, at \*5 (Fed. Cl. Spec. Mstr. Mar. 5, 2021); Desai v. Sec'y of Health & Hum. Servs., No 14-0811V, 2020 WL 4919777, at \*14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Hum. Servs., No. 18-0559V, 2020 WL 1870268, at \*5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Hum. Servs., No. 17-0990V, 2018 WL 6718629, at \*4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

<sup>&</sup>lt;sup>9</sup> In a recent Ruling by another special master, the pharmacist who had administered the relevant vaccination actually testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, based upon the assumption that most vaccinees are right-handed. *Mezzacapo v. Sec'y of Health & Hum. Servs.*, No. 18-1977V, 2021 WL 1940435, at \*4 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

are handwritten – meaning those that require specific action on the part of the vaccine administrator, as opposed to those that are automatically generated by a computerized system. See, e.g., Rizvi, 2022 WL 2284311, at \*5; Rodgers v. Sec'y of Health & Hum. Servs., No. 18-0559V, 2020 WL 1870268, at \*5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020).

The vaccine administration form at issue in this case is an automated entry in a computerized system. It is the only evidence in this case that contradicts Petitioner's assertion and supports a finding of left arm situs. Given the general unreliability of an automated vaccination record, and when weighed against Petitioner's clear, consistent, and close-in-time reports of right shoulder pain following her receipt of a flu vaccine in that arm, I find by a preponderance of the evidence that Petitioner received her September 26, 2019 flu vaccine in her right arm.

#### Conclusion

Petitioner has established that she received the subject flu vaccination in her right shoulder, as alleged. Additionally, Petitioner has provided preponderant evidence that the onset of her shoulder pain occurred within 48 hours of vaccination.

Accordingly, I encourage the parties to make an attempt at settlement. Petitioner shall file a joint status report stating that she has provided Respondent with a revised settlement demand for her right-sided Table claim and the parties' efforts towards informal resolution, by no later than Monday, July 1, 2024.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran Chief Special Master